

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.: 10/049,427
Applicant: Thor
Filed: May 6, 2002
TC/A.U.: 1617
Examiner: Yong Chong
Atty. File No.: 4220-78-PUS
Customer No.: **22442**

Confirmation No. 1087

Filed Electronically

Board of Patent Appeals and Interferences
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

RESPONSE TO NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF

Sir,

This Response is filed in reply to the Notification of Non-Compliant Appeal Brief mailed April 27, 2007. In compliance with MPEP § 1205.03 (B) this paper provides only a summary of the claimed subject matter as required by 37 CFR 41.37(c)(1)(v). This summary, which identifies and maps each independent claim (37, 40, 51, 52, 53 and 54) to the specification by page and line number and to the drawings, begins on page 2 of this paper.

This response is filed within 30 days of the mailing date of the Notification, and Applicants therefore believe this response is timely filed and no fees are due. In the event any fees are due, please debit Deposit Account No. 19-1970.

Respectfully submitted,
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Date: May 25, 2007

(v) Summary of Claimed Subject Matter (Amended).

The currently pending independent claims 37, 40, 51, 52, 53, and 54, recited in the Claims Appendix hereto, are directed to methods of treating or managing the sexual dysfunction of premature ejaculation in a male mammal by the administration of dapoxetine to the mammal (see, Specification at page 1, lines 5-10 and page 10, lines 4-10).

One embodiment, which is the subject of Independent Claim 37, is directed to a method of treating or managing sexual dysfunction in a mammal in need of treatment which comprises administering on an as-needed basis to the mammal a therapeutically effective amount of dapoxetine or a pharmaceutically acceptable salt thereof (page 7, lines 5-10; page 10, lines 15-21), wherein the sexual dysfunction is premature ejaculation (page 7, lines 2-4; page 19, lines 30-34), wherein the mammal is a human male (page 7, lines 1-3), and wherein said administration of dapoxetine is effective for treating or managing premature ejaculation in the absence of priming doses (page 6, lines 3-10 and 32-34; page 19, lines 20-25).

A related embodiment, which is the subject of Independent Claim 40, is directed to a method of treating or managing sexual dysfunction in a mammal in need of treatment which comprises administering on an as-needed basis to the mammal a therapeutically effective amount of dapoxetine or a pharmaceutically acceptable salt thereof (page 7, lines 5-10; page 10, lines 15-21), wherein the sexual dysfunction is premature ejaculation (page 7, lines 2-4; page 19, lines 30-34), wherein the mammal is a human male (page 7, lines 1-3), wherein dapoxetine is administered immediately prior to, to about 4 hours prior to a sexual activity (page 6, lines 28-29; page 20, lines 18-19; figure 2) and wherein said administration of dapoxetine is effective for treating or managing premature ejaculation in the absence of priming doses (page 6, lines 3-10 and 32-34; page 19, lines 20-25).

Another embodiment, which is the subject of Independent Claim 51, is directed to a method of treating premature ejaculation in a human male (page 7, lines 1-6) which comprises administering orally (page 16, lines 3-5) to the human male (page 7, lines 2-3) about 0.01 mg to about 200 mg of dapoxetine or a pharmaceutically acceptable salt

thereof (page 21, line 1) immediately prior to, to about 4 hours prior to a sexual activity (page 6, lines 28-29; page 20, lines 18-19; figure 2), wherein said administration of dapoxetine is effective for treating premature ejaculation in the absence of priming doses (page 6, lines 3-10 and 32-34; page 19, lines 20-25).

Another embodiment, which is the subject of Independent Claim 52, is directed to a method of treating premature ejaculation in a human male (page 7, lines 1-6) which comprises administering orally (page 16, lines 3-5) to the human male (page 7, lines 2-3) about 0.01 mg to about 200 mg of dapoxetine or a pharmaceutically acceptable salt thereof (page 21, line 1) immediately prior to, to about 3 hours prior to a sexual activity (see original claim 52 at page 46, lines 16-19), wherein said administration of dapoxetine is effective for treating premature ejaculation in the absence of priming doses (page 6, lines 3-10 and 32-34; page 19, lines 20-25).

Another embodiment, which is the subject of Independent Claim 53, is directed to a method of treating premature ejaculation in a human male (page 7, lines 1-6) which comprises administering orally (page 16, lines 3-5) to the human male (page 7, lines 2-3) about 0.01 mg to about 200 mg of dapoxetine or a pharmaceutically acceptable salt thereof (page 21, line 1) about 30 minutes to about 3 hours prior to a sexual activity (original claim 53 at page 46, lines 20-23), wherein said administration of dapoxetine is effective for treating premature ejaculation in the absence of priming doses (page 6, lines 3-10 and 32-34; page 19, lines 20-25).

Another embodiment, which is the subject of Independent Claim 54, is directed to a method of treating premature ejaculation in a human male (page 7, lines 1-6) which comprises administering orally (page 16, lines 3-5) to the human male (page 7, lines 2-3) about 0.01 mg to about 200 mg of dapoxetine or a pharmaceutically acceptable salt thereof (page 21, line 1) about 30 minutes to about 3 hours prior to a sexual activity (original claim 53 at page 46, lines 20-23), wherein said administration of dapoxetine is effective for treating premature ejaculation in the absence of priming doses (page 6, lines 3-10 and 32-34; page 19, lines 20-25).

Another embodiment, which is the subject of Independent Claim 54, is directed to a method of treating premature ejaculation in a human male (page 7, lines 1-6) which comprises administering orally (page 16, lines 3-5) to the human male (page 7, lines 2-3)

about 0.01 mg to about 200 mg of dapoxetine or a pharmaceutically acceptable salt thereof (page 21, line 1) immediately prior to a sexual activity (page 6, lines 29-31; original claim 54 at page 46, lines 24-27), wherein said administration of dapoxetine is effective for treating premature ejaculation in the absence of priming doses (page 6, lines 3-10 and 32-34; page 19, lines 20-25).